IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

SANDOZ INC. and RAREGEN, LLC *Plaintiffs*, v. UNITED THERAPEUTICS CORP. and SMITHS MEDICAL ASD, INC. *Defendants*.	Case No. 19-cv-10170-BRM-LHG **MEMORANDUM IN SUPPORT OF PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION** **Oral Argument Requested** *CONTAINS INFORMATION DESIGNATED AS "HIGHLY CONFIDENTIAL" PURSUANT TO STIPULATED CONFIDENTIALITY ORDER* Document electronically filed

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PRELIMINARY STATEMENT

The relevant facts are undisputed. [redacted] designed to impede competition between Plaintiffs' generic treprostinil and the brand-name alternative, Remodulin, which is sold by Defendant United Therapeutics Corporation ("UTC"). Defendants' anticompetitive scheme was reduced to a series of written agreements, successfully blocked Plaintiffs' cheaper generic drug from being accessed by patients, and artificially inflated the cost of patient care. Defendants' actions have therefore harmed competition, the public, and Plaintiffs.

Doctors prescribe subcutaneous and intravenous injections of treprostinil to treat severe cases of pulmonary arterial hypertension ("PAH"). Most patients in the United States who receive treprostinil injections have them administered subcutaneously, and the CADD-MS 3 pump is the only pump available in the United States to administer those treatments. The pump infuses small doses of treprostinil under a patient's skin from a disposable syringe, which is called a cartridge. Defendant Smiths Medical ASD, Inc. ("Smiths") manufactures the cartridges, and CADD-MS 3 pumps are useless without them. UTC and Smiths conspired to ensure that only patients using Remodulin could access cartridges, making it impossible for patients to receive subcutaneous treatments with Plaintiffs' generic treprostinil

injection.

On the eve of generic entry, UTC asked Smiths to [redacted] With patient care hanging in the balance, the pharmacies had no choice but to give in.

As a result of Defendants' efforts, in early 2019, Plaintiffs started hearing from the pharmacies—for the first time—that cartridges were suddenly unavailable, even though cartridges previously had been available without restriction for many years. [redacted] Without access to cartridges, Plaintiffs' generic drug is not an option for patients who have been prescribed subcutaneous injections.

The agreements between UTC, Smiths, and the specialty pharmacies (the "Restraints") are anticompetitive and have insulated Remodulin from meaningful competition. The price of Plaintiffs' generic drug is [redacted]% less than the price of Remodulin. That means the Restraints artificially inflate the cost of subcutaneous treatments by forcing all subcutaneous patients to use UTC's higher-cost drug.

To stop Defendants' illegal scheme and immediately open up the benefits of competition between Remodulin and Plaintiffs' generic alternative, Plaintiffs respectfully ask the Court to preliminarily enjoin Defendants from enforcing the Restraints. Even with only targeted, expedited discovery, the record confirms that

all elements of the preliminary injunction inquiry weigh in favor of Plaintiffs' requested relief.

STATEMENT OF FACTS[1]

I. Patients Need Cartridges to Receive Subcutaneous PAH Treatments

A. Injected Treprostinil Is the Only Subcutaneous PAH Treatment

PAH is a chronic disorder that causes high blood pressure in the arteries leading to the lungs. Roberts Decl. ¶¶ 14-18. It has no cure. Watson 64:6-13.[2]

Remodulin is manufactured by UTC, and it is prescribed to treat patients with severe PAH symptoms. Benkowitz 44:3-19; Roberts Decl. ¶¶ 18, 27. Remodulin can be administered through subcutaneous infusions under the patient's skin or intravenously. Watson 59:10-15; Roberts Decl. ¶ 27. Subcutaneous infusions are the preferred mode of administration. Roberts Decl. ¶ 28; Waxman 139:19-140:2, 142:5-9. Intravenous injections are more invasive than subcutaneous infusions and carry a higher risk of infection. Roberts Decl. ¶¶ 28, 39; Waxman 161:4-11; Watson 60:4-61:21.

Remodulin was first sold in the United States in 2002. Ex. 1000 at 3. Until March 25, 2019, there was no generic alternative. deGoa Aff. ¶¶ 2, 32. Remodulin

[1] Plaintiffs will submit to the Court a USB drive that contains an electronic version of this brief with hyperlinks to the underlying evidence.

[2] Plaintiffs' deposition designations are attached to the Declaration of Ethan Glass ("Glass Decl."), in the form of annotated deposition excerpts. Pages without designated testimony have been omitted. For the convenience of the Court, Plaintiffs also created a brief summary of each witness's background. Glass Decl., Ex. A.

and Plaintiffs' generic treprostinil are therapeutically equivalent. Spina Decl. ¶ 6. They are the only PAH treatments that can be administered subcutaneously. Watson 18:24-25, 63:10-13, 65:23-66:2; Roberts Decl. ¶ 37.

There are only two pharmacies in the United States that dispense treprostinil injections: Accredo Health Group, Inc. ("Accredo") and CVS Specialty Pharmacy ("CVS"). Watson 45:16-46:10; deGoa Aff. ¶ 6. Accredo and CVS also provide pumps, cartridges, and other supplies to PAH patients, and train patients to administer their treatments. deGoa Aff. ¶¶ 6-7. Accredo services approximately 80% of the patient population on injected treprostinil in the United States. *Id.* ¶ 7.

B. The CADD-MS 3 Is the Only Pump Used in the United States to Administer Subcutaneous Treprostinil Infusions

Smiths' CADD-MS 3 pump is the only pump available in the United States to administer subcutaneous infusions of treprostinil. UTC 30(b)(6) (Gray) 184:4-185:4; Walker 89:17-90:5, 138:4-18, 211:3-212:2. [redacted] UTC 30(b)(6) (Gray) 11:24-13:8; Walker 55:10-15, 89:17-25; Watson 159:19-160:4. Accredo and CVS own CADD-MS 3 pumps and rent them to patients. Ex. 1002; Watson 202:15-203:3. [redacted] Ex. 1003; Walker 21:4-9; Quinn 55:7-16. [redacted]. Ex. 1004 at 076; Quinn 55:7-56:2.

CADD-MS 3 pumps deliver infusions of treprostinil under a patient's skin

from a disposable syringe, which is called a cartridge. Quinn 56:3-57:5, 57:17-20. When a new cartridge is needed, a patient removes the used cartridge from their pump, disposes the used cartridge, fills a replacement cartridge with treprostinil, and places it in their pump. Ex. 1005 at 436, 450-53. Without cartridges, the pumps are useless. Gencheff 17:3-18; Rhodes 91:19-24; Quinn 56:3-24. Prior to 2019, [redacted] Donovan 48:20-49:18, 129:11-24.

C. Plaintiffs Sell the First Generic Version of Remodulin

Sandoz filed the first ANDA for generic Remodulin in 2011. Spina Decl. ¶ 5. UTC sued Sandoz for patent infringement, and the parties settled in September 2015. *Id.* [redacted] The FDA approved Sandoz' ANDA in November 2017. Spina Decl. ¶ 6. Sandoz is entitled to a six-month exclusivity period following its first sale, and it will be the only generic version of Remodulin on the market during that time. *Id.* ¶ 7.

Sandoz partnered with RareGen in August 2018 to commercialize its generic

treprostinil injection. Sandoz is responsible for ensuring there is sufficient supply of generic treprostinil. *Id.* ¶ 8. RareGen is responsible for commercializing generic treprostinil, including detailing and promoting its appropriate use. deGoa Aff. ¶ 3. RareGen made an upfront investment of $[redacted] million in the partnership, Ex. AA at 451, and it has already spent [redacted] of dollars commercializing the product, deGoa Aff. ¶ 4. RareGen earns a greater percentage of net profits from generic treprostinil sales than Sandoz. Ex. AA at 451-52.

II. There Were No Restrictions on Cartridge Use Before 2019

[redacted] Ex. 154; Watson 165:23-166:2. [redacted] Walker 54:14-19. [redacted] Watson 158:25-160:4; UTC 30(b)(6) (Gray) 11:24-13:8. [redacted] Ex. 67; Watson 175:21-176:4. [redacted] Ex. 67 at 003. [redacted]

[redacted] *Id*. at 002. [redacted]

[redacted] *Id*. at 003 (¶ 6). [redacted]

[redacted] *Id*.

[redacted] Watson 200:25-201:8; Walker 17:22-18:9, 22:15-21, 29:20-30:7; Rhodes 115:15-116:9.

[redacted] Ex. 205; Walker 143:14-145:14. [redacted] Ex. 206 at 954; Ex. 207; Walker 163:20-25. [redacted] Ex. 210 at 954; Ex. 463; Walker 181:21-182:13; Donovan 112:4-22, 113:23-114:17. [redacted] Ex. 202.

[redacted] Ex. 55 at 905, 919-21; Rhodes 116:18-117:1. [redacted] Rhodes 122:23-124:23. [redacted]

[redacted] Walker 70:10-72:21. [redacted]

Ex. 90 at 416; Ex. 466 at 642-43; Ex. 467 at 813-14; Ex. 468; Ex. 469; Ex. 470.

[redacted]. Ex. 722; Ex. 724.

III. UTC and Smiths Conspired to Suppress Generic Competition in 2019

A. [redacted]

By the fall of 2018, Plaintiffs were negotiating agreements with Accredo and CVS under which the pharmacies would dispense generic treprostinil and provide related support services to patients. deGoa Aff. ¶ 8. Accredo assured Plaintiffs that it owned enough older, unencumbered pumps to serve generic treprostinil patients. *Id.* ¶ 11; Ex. 357; Ex. DD. During that same time period, RareGen was preparing marketing materials and its sales team was already meeting with clinicians to explain the benefits of generic treprostinil. deGoa Aff. ¶ 8.

[redacted] Ex. 705

at #74; *see also id*. at #1, #15; Benkowitz 149:24-150:19. [redacted]

[redacted] Benkowitz 149:8-14. [redacted]

[redacted] Ex. 61.

[redacted]

Ex. 91.

[redacted]

[redacted] Ex. 87 at 152. [redacted]

[redacted] Rhodes said:

[redacted] Ex.

459 at 966. [redacted]

[redacted] Ex. 705 at #76.

B. In December 2018, [redacted]

On December 17, 2018, Rhodes asked Gencheff to [redacted] Ex. 89 at 381. [redacted] *Id*. at 379-80; Rhodes 137:21-138:7. Gencheff replied that [redacted] Ex. 89 at 378-79; *see also* Ex. 59 at 364.

[redacted] Ex. 90 at 416, [redacted] 145:21-146:1. [redacted] Ex. 90 at 416; Ex. 92 at 124. [redacted] Donovan 46:19-47:10, 82:18-83:2, 218:8-219:5, 220:22-221:17; Gencheff 290:6-20; Benkowitz 172:7-173:8; Ex. 1007 [redacted] Donovan 179:16-24. [redacted] Ex. 90 at 416.

[redacted] Ex. 89 at 378; Ex. 93 at 130;

Ex. 95 at 259; Gencheff 244:25-245:4, 246:24-248:10, 259:1-15, 263:6-264:10. [redacted], Ex. 475, [redacted] Ex. 488, and, for the first time, [redacted], Ex. 477 [redacted]; Donovan 208:12-24.

[redacted] Ex. 96 at 385 [redacted]); Ex. 98 at 766 [redacted]; Ex. 483 [redacted] Ex. 98 at 766; deGoa Aff. ¶ 14; Ex. GG; Donovan 247:4-8, 247:19-248:25, 250:6-23, 251:20-252:17, 270:5-18, 271:8-272:16, 272:25-274:7. [redacted] Ex. 98 at 765 [redacted]; deGoa Aff. ¶ 14; Ex. II; Donovan 246:9-17, 247:4-8, 251:2-7, 252:11-17. [redacted] Ex. 472 at 264; Donovan 146:20-147:11.

C. With Patient Health at Risk, [redacted]

[redacted]

[redacted]. Ex. 478 [redacted]

[redacted]

[redacted]

[redacted]; Ex. 489 at 769 (same); Donovan 211:7-19, 213:7-15, 302:18-303:4. [redacted]

[redacted] Ex. 71; Ex. 72. The notice, [redacted]

[redacted], stated:

> [redacted]

See, *e.g.*, Ex. 71 at 759. [redacted]

[redacted] Donovan 260:16-261:18; Walker 79:13-21.

> [redacted]

[redacted] Ex. 485 at 194 [redacted]

[redacted]

[redacted]

[redacted]

[redacted][3] Ex. 490 at 235.

> [redacted]

[3] [redacted] Ex. 455 at 464; Donovan 31:23-32:10.

[redacted] Ex. 705 at #53 [redacted]; Ex. 93 at 132. [redacted] Ex. 151 at 215 [redacted]); Ex. 458 [redacted]; Donovan 93:8-94:22. [redacted] Ex. 151 at 216 [redacted]), at 215 [redacted]. Michael Benkowitz, UTC's President, [redacted] Benkowitz 167:24-169:25; *cf.* Gencheff 305:2-9 [redacted]

As the launch of generic treprostinil grew closer, UTC became [redacted] Ex. 61 at 677. [redacted] *Id.*; Benkowitz 188:7-13. [redacted]

[redacted] Ex. 61 at 677. That was true. [redacted] Ex 100 at 670.

[redacted] *See*, *e.g.*, Ex. 1009 at 898 [redacted]; Ex. 1010 [redacted]. That reckless conduct placed patient safety at risk:

- On March 1, CVS wrote to Smiths that [redacted] Ex. 152.
- On March 6, CVS wrote to Smiths that [redacted] Ex. 456 at 589.
- On March 12, Accredo wrote to Smiths that its [redacted] Ex. 479 at 563; *see also* Ex. 708 at 528.

And with patient health on the line, these tactics wore down Accredo and CVS. [redacted] Ex. 65 (Accredo); Ex. 84 (CVS). But Smiths never [redacted]. Gencheff 42:14-43:13, 46:2-48:16.

D. ***[redacted], Restrictions on Cartridge Use Went Into Effect***

[redacted]

[redacted] Ex. 56. [redacted]

[redacted] *Id.* ¶ 1.a.6; Rhodes 109:19-110:18.

[redacted]

[redacted]. Gencheff 25:10-16, 26:5-8. [redacted]

[redacted] Ex. 725;

Ex. 723. [redacted]

[redacted]

[redacted]. UTC 30(b)(6) (Gray) 179:15-20, 182:8-24.

IV. [redacted]

[redacted]

[redacted] *Supra* at 9-12. [redacted]

[redacted] *See*, *e.g.*, Ex. 84

at 873 [redacted]

[redacted]; Donovan 109:6-25, 113:23-114:17, 227:5-19, 253:24-254:8.

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

Ex. 475 at 251 (emphasis added). [redacted]

[redacted]

See Ex. 99 at 133 [redacted]

[redacted]

Donovan 223:22-224:10; *id*. at 109:6-109:17, 196:14-197:8, 203:6-204:10; Ex. 480.

V. The Restraints Artificially Inflate the Price of Injected Treprostinil

Sandoz and RareGen launched generic treprostinil sales on March 25, 2019. deGoa Aff. ¶ 32. Plaintiffs sell generic treprostinil at a price that is about [redacted] less than the price of Remodulin. Rao Report ¶ 79. [redacted]

[redacted]

As a result of the Restraints, generic treprostinil is only available to patients receiving intravenous treatments. deGoa Aff. ¶ 32. The fact that generic treprostinil is available to patients for intravenous administration, but not subcutaneous, has resulted in a price differential for treprostinil sold for these two different administration methods. Rao Report ¶ 82. Following generic entry, in the second quarter of 2019, the weighted average price of treprostinil used for subcutaneous treatments was $[redacted] per mg—approximately [redacted]% higher than the price for treprostinil used for intravenous treatments. *Id.* The projected annual cost savings of having a generic subcutaneous treprostinil available for patients will be millions of dollars per year. *Id.* ¶ 102, Tab 14.

As of August 31, 2019, fewer than [redacted] patients are receiving generic treprostinil treatments (all of whom are administering the drug intravenously). deGoa Aff. ¶ 33. In contrast, in December 2018, there were [redacted] patients receiving Remodulin through intravenous treatments, Ex. 1011 (showing [redacted] patients serviced by Accredo); Ex. 1012 (showing [redacted] patients serviced by CVS), and [redacted] patients receiving subcutaneous Remodulin treatments, Rao Report at Tab 14.

More patients would receive generic treprostinil if the Restraints did not exist. deGoa Aff. ¶¶ 34-36. It is common for payors to adopt policies requiring a pharmacy to dispense a generic unless the prescriber indicates the brand drug should be "dispensed as written." *Id.* ¶ 35. Payors have told Plaintiffs they cannot implement

a generic-first policy for only intravenous treatments, so they are waiting until generic treprostinil is available for both subcutaneous and intravenous treatments. *Id.* Thus, the Restraints are impeding generic treprostinil sales for both subcutaneous and intravenous patients and artificially inflating the cost of care.

ARGUMENT

"Four factors are considered in determining whether to grant a preliminary injunction: (1) whether the movant has a reasonable probability of success on the merits; (2) whether the movant will be irreparably harmed by denying the injunction; (3) whether there will be greater harm to the nonmoving party if the injunction is granted; and (4) whether granting the injunction is in the public interest." *Highmark, Inc. v. UPMC Health Plan*, 276 F.3d 160, 170-71 (3d Cir. 2001). Here, all four factors weigh heavily in favor of a preliminary injunction.

I. Plaintiffs Are Likely to Succeed on the Merits

Plaintiffs seek a preliminary injunction based on only their Sherman Act claims. *See* 15 U.S.C. §§ 1-2. Although those claims are evaluated under the "rule of reason," *Eisai, Inc. v. Sanofi Aventis U.S., LLC*, 821 F.3d 394, 403 (3d Cir. 2016); *ZF Meritor, LLC v. Eaton Corp.*, 696 F.3d 254, 281 (3d Cir. 2012), the evidence of anticompetitive effects here is so strong that the Court need not look past how the agreements impede competition with Remodulin, *Cal. Dental Ass'n v. F.T.C.*, 526 U.S. 756, 770 (1999) ("Quick-look" analysis, an abbreviated inquiry, "carries the

day when the great likelihood of anticompetitive effects can easily be ascertained").

Nevertheless, even if the Court conducts a full-blown rule of reason analysis, the record confirms Defendants' "restrictive practice should be prohibited as imposing an unreasonable restraint on competition." *United States v. Brown Univ.*, 5 F.3d 658, 668 (3d Cir. 1993) (citation omitted). The record shows both (1) direct proof of actual anticompetitive effects, which include higher prices, reduced output, or decreased quality, and (2) indirect proof of "market power," which is "the ability to raise prices above those that would prevail in a competitive market." *Id*. Based on that showing, the burden shifts to the Defendants "to show that the challenged conduct promotes a sufficiently pro-competitive objective." *Id*. at 669. Defendants cannot meet that burden; there are no pro-competitive justifications for the Restraints and there are less restrictive alternatives that would not impact competition.

A. The Restraints Have Harmed Competition

1. Direct Evidence Shows the Restraints Cause Higher Prices

"Actual anticompetitive effects can be shown through reduced output, increased prices . . . and loss of consumer choice." *Deborah Heart & Lung Ctr. v. Penn Presbyterian Med. Ctr.*, 2011 WL 6935276, at *7 (D.N.J. Dec. 30, 2011). There is ample evidence the Restraints increase prices and reduce consumer choice.

The price for intravenous treprostinil treatments declined quickly and substantially following generic entry. Patients who are receiving intravenous

treatments do not need cartridges, which means they can be dispensed either Remodulin or generic treprostinil. Specialty pharmacies pay [redacted] less for generic treprostinil than they do for Remodulin, Rao Report ¶ 79, which is why the average price per milligram of intravenously injected treprostinil declined by [redacted] in the quarter following generic entry, *id*. ¶ 82 & Tab 9. [redacted] it has driven down the cost to treat intravenous patients.

The same thing cannot be said for the costs associated with treating patients receiving subcutaneous infusions. As a result of the Restraints, patients who have been prescribed subcutaneously-infused treprostinil have only one option: Remodulin. [redacted]

In the absence of the Restraints, the price for subcutaneously-administered treprostinil should have fallen to the same level as the price for intravenous treatments. As Plaintiffs' economic expert, Dr. Mohan Rao, will testify, the price differential between the two methods of administration is direct economic evidence that the Restraints have significant anticompetitive effects. Rao Report ¶¶ 78-91.

2. Indirect Evidence Shows the Restraints Substantially Foreclose Competition

"[P]roof of the defendant's market power" can also "act[] as a proxy for

anticompetitive effect." *Deborah Heart & Lung Ctr.*, 2011 WL 6935276, at *7. "One indirectly proves market power by (1) defining the relevant market, (2) establishing that the defendant has a large share of that market, and (3) showing that there are barriers to entry which protect the defendant's large market share." *Graco Inc. v. PMC Glob., Inc.*, 2012 WL 762448, at *8 (D.N.J. Mar. 6, 2012). And the plaintiff must also show that the challenged conduct has anticompetitive effects. *See LePage's Inc. v. 3M*, 324 F.3d 141, 158-62 (3d Cir. 2003).

As explained below, Plaintiffs can prove (1) UTC is a monopolist; (2) its market position is protected by high barriers to entry; (3) with assistance from Smiths, UTC implemented exclusive-dealing contracts; (4) those contracts substantially foreclosed competition; and (5) as a result, prices have been artificially inflated. That is more than enough to show Plaintiffs "can win on the merits." *See Reilly v. City of Harrisburg*, 858 F.3d 173, 179 (3d Cir. 2017).

a. Subcutaneously Injected Treprostinil and Injected Prostacyclins Are Relevant Product Markets

"[W]here a plaintiff demonstrates direct evidence of actual anticompetitive effects, the plaintiff's burden is diminished and it must only demonstrate the rough contours of a relevant market." *Deborah Heart & Lung Ctr.*, 2011 WL 6935276, at *7. Plaintiffs have proof of direct anticompetitive effects, *supra* at 20-21, and can easily identify the "rough contours" of the markets affected by Defendants' conduct.

"[A] market's outer boundaries are determined by the reasonable

interchangeability of use between a product and its substitute, or by their cross-elasticity of demand." *Broadcom Corp. v. Qualcomm Inc.*, 501 F.3d 297, 307 (3d Cir. 2007). "When assessing reasonable interchangeability, factors to be considered include price, use, and qualities. Reasonable interchangeability is also indicated by cross-elasticity of demand between the product itself and substitutes for it." *Queen City Pizza, Inc. v. Domino's Pizza, Inc.*, 124 F.3d 430, 437 (3d Cir. 1997). "Whether products are interchangeable is analyzed from the customers' perspective." *Graco*, 2012 WL 762448, at *8.

The United States Is a Relevant Geographic Market. "The relevant geographic market is the area in which a potential buyer may rationally look for the goods or services he or she seeks." *Tunis Bros. Co. v. Ford Motor Co.*, 952 F.2d 715, 726 (3d Cir. 1991). Patients in the United States can only be dispensed FDA-approved drugs, and thus, the relevant geographic market here is the United States. *See Ethypharm S.A. France v. Abbott Labs.*, 707 F.3d 223, 236 (3d Cir. 2013).

Subcutaneously Injected Treprostinil Is a Relevant Product Market. The price, use, and characteristics of subcutaneously-administered treprostinil show that it is a relevant product market. Injected treprostinil is the only PAH treatment that can be administered by subcutaneous infusion (*i.e.*, under the skin). *Supra* at 4-5. And subcutaneous infusions are the preferred method of administering injected treprostinil because subcutaneous treatments (1) carry a lower risk of infection than

intravenous treatments; and (2) allow for increased patient mobility and quality of life. Roberts Decl. ¶ 28. Given these unique traits, patients who are prescribed subcutaneously-administered treprostinil have no other close alternatives. That is why [redacted] *See*, *e.g.*, Benkowitz 58:8-60:1, 126:6-24; Rao Report ¶ 73.

Two key pieces of real-world evidence confirm that there are no close substitutes for subcutaneously-administered treprostinil. [redacted] intravenous treatments were a close substitute for subcutaneous patients, that investment would have made no economic sense—UTC could have just transitioned subcutaneous patients to intravenous treatment. ***Second***, even though generic treprostinil is cheaper than Remodulin and has now been available as an intravenous treatment for months, physicians have not transitioned subcutaneous patients to intravenous treatments to take advantage of the lower cost of care. *See* Rao Report ¶¶ 82-83. Thus, there is no evidence of cross-elasticity of demand between subcutaneously-administered treprostinil and any other product.

Cf. Mylan Pharm. Inc. v. Warner Chilcott Pub. Ltd. Co., 838 F.3d 421, 437 (3d Cir. 2016) (evidence of cross-elasticity, specifically, "that Defendants responded to the market's reaction to their prices with sales promotions in an effort to increase their ability to compete with other tetracyclines" and "when Defendants increased the price of Doryx, its sales decreased, and the sales of other tetracyclines increased," showed the relevant market was "oral tetracyclines prescribed to treat acne").[4]

For all these reasons, subcutaneously-administered treprostinil is a relevant antitrust market. And as discussed below, it also is a submarket within a broader market of ***all*** injected prostacyclins, including injected treprostinil. *See U.S. Horticultural Supply v. Scotts Co.*, 367 F. App'x 305, 310 (3d Cir. 2010) (submarkets may be defined based on, *inter alia*, "the product's peculiar characteristics and uses, unique production facilities, [and] distinct customers").

Injected Prostacyclins Are Also a Relevant Product Market. Even though treprostinil is the only PAH treatment that can be administered through subcutaneous infusions, there are other PAH treatments that can be injected intravenously, just like Remodulin and generic treprostinil. Those other treatments are generic

[4] The evidence of cross-elasticity of demand and drug interchangeability in *Mylan* is just one reason that case is distinguishable from this one. 888 F.3d at 435-37. The Third Circuit also found Mylan "failed to provide direct evidence of monopoly power" because its experts gave no "substantiated quantitative analysis showing that Defendants maintained high price-cost margins." *Id.* at 434-35. Here, there is direct evidence the Restraints allowed UTC to maintain supra-competitive pricing. Rao Report ¶ 94.

epoprostenol, Flolan, and Veletri. Watson 61:15-63:18; Roberts Decl. ¶ 21.

These pharmaceuticals, called injected prostacyclins, all have similar use cases and characteristics because (1) they all can be administered by intravenous injections, Watson 61:15-63:18; Roberts Decl. ¶¶ 21-23; (2) they all address the prostacyclin pathway, Roberts Decl. ¶ 21; and (3) they all treat patients with severe PAH symptoms, *id*. ¶¶ 35-36. While there are "pathways" to treat PAH symptoms that are not prostacyclins (the nitric oxide pathway and the endothelium pathway), Benkowitz 50:11-51:2; *see also* Roberts Decl. ¶ 21, injected prostacyclins are "the only first-choice therapies" considered by physicians for treating patients with severe PAH symptoms, Roberts Decl. ¶¶ 35-39. Given these shared characteristics and use cases, the market composed of injected treprostinil, generic epoprostenol, Flolan, and Veletri, which UTC calls [redacted] Benkowitz 53:24-54:12, is a relevant antitrust product market.

Oral and Inhaled PAH Treatments Are Not in the Same Relevant Product Market as Remodulin. UTC claims Remodulin competes with all PAH treatments, including oral and inhaled therapies. Ex. 57. That is not true. The differences in price, use, and characteristics of oral and inhaled PAH treatments, when compared to injected treatments, confirm they are not part of the same antitrust markets.

"As a general matter and accepted consensus clinical practice, oral and inhaled therapies are not substituted for injected therapies in patients for whom injected

drugs are the best therapeutic choice." Roberts Decl. ¶ 23; *see also* Waxman 82:18-20, 93:2-94:7, 98:22-99:14, 100:15-103:5, 106:19-107:24, 111:2-19. [redacted] Except for subcutaneously-infused treprostinil, injected treatments require surgical insertion of an intravenous catheter in the patient's chest. Ex. 1000 at 7; Watson 60:18-61:1. Oral and inhaled therapies are used to treat less severe symptoms than Remodulin, and they are not recommended for patients with "Class IV" symptoms. Roberts Decl. ¶ 38. And there is no evidence of cross-elasticity of demand between Remodulin and these treatments, because there is no evidence the prices of oral or inhaled products affect the price of Remodulin in any way. Benkowitz 79:15-81:5, 91:2-6, 91:20-92:17, 102:7-105:16, 105:25-108:1. Indeed, Defendants' economic expert, Dr. Eric Gaier, conceded that [redacted] Gaier 409:18-410:13.

"[O]ral and inhaled therapies are generally prescribed to patients with less severe symptoms, although those patients may also remain on those therapies to complement injected therapies as their symptoms become more severe." Roberts Decl. ¶ 23. Contrary to Defendants' arguments, "[t]his demonstrates that these products are complements, rather than substitutes, so a distinct market exists for each." *U.S. Horticultural Supply*, 367 F. App'x at 310. [redacted]

[redacted] Thus, patients do not substitute between them, and Remodulin and these drugs are not part of the same relevant antitrust market.

b. FDA Regulations Are a Substantial Barrier to Entry

FDA regulations are a substantial barrier to entering both relevant markets here. *See Ethypharm*, 707 F.2d at 236 (FDA regulations are a "high legal barrier to entry"); *Fed. Trade Comm'n v. AbbVie Inc.*, 329 F. Supp. 3d 98, 135-36 (E.D. Pa. 2018). Confirming the significance of this barrier to entry, Plaintiffs' generic treprostinil is the first generic version of Remodulin to launch since 2002.

c. UTC Has Market Power

In a market with high barriers to entry, a share significantly in excess of 55% is *prima facie* evidence of market power. *United States v. Dentsply Int'l, Inc.*, 399 F.3d 181, 187 (3d Cir. 2005); *see also Fineman v. Armstrong World Indus., Inc.*, 980 F.2d 171, 202 (3d Cir. 1992).

UTC possesses market power in both relevant markets because its market share is much higher than 55% and it is protected by high barriers to entry. The Restraints prohibit patients receiving subcutaneous treatment from accessing Plaintiffs' generic treprostinil, so UTC's share of the subcutaneously-administered

[redacted]

d. The Restraints Have Anticompetitive Effects

"When a monopolist's actions are designed to prevent one or more new or potential competitors from gaining a foothold in the market by exclusionary, i.e. predatory, conduct, its success in that goal is not only injurious to the potential competitor but also to competition in general." *LePage's, Inc. v. 3M*, 324 F.3d 141, 159 (3d Cir. 2003). That is what has happened here. The Restraints prevent Plaintiffs' product from reaching subcutaneous patients, and as a result, they cannot "pose a real threat to [UTC's] business." *ZF Meritor*, 696 F.3d at 286; *see also id.* at 284 ("[I]f the defendant occupies a dominant position in the market, its exclusive dealing arrangements invariably have the power to exclude rivals.").

When evaluating anticompetitive effects of exclusive-dealing relationships, "courts must look to the monopolist's conduct taken as a whole rather than considering each aspect in isolation." *LePage's*, 324 F.3d at 162. "The relevant inquiry is the anticompetitive effect of [Defendants'] exclusionary practices

considered together." *Id.* In this case, the Court should therefore consider the combined effects of UTC's [redacted]

"The test is not total foreclosure, but whether the challenged practices bar a substantial number of rivals or severely restrict the market's ambit." *Dentsply*, 399 F.3d at 191. Foreclosure of "40% or 50% share [is] usually required in order to establish a § 1 violation," but courts have held that exclusive dealing arrangements by a monopolist can violate Section 2 even if a smaller share of the market is impacted. *LePage's*, 324 F.3d at 159; *see also United States v. Microsoft Corp.*, 253 F.3d 34, 70 (D.C. Cir. 2001); *McWane, Inc. v. F.T.C.*, 783 F.3d 814, 838 (11th Cir. 2015). These standards are easily satisfied here.

The Restraints foreclose 100% of the market for subcutaneously-administered treprostinil. UTC holds a 100% share of that market because Remodulin is the only choice. The Restraints prevent patients from obtaining cartridges, and without cartridges, patients cannot receive subcutaneous infusions of generic treprostinil. That amounts to complete foreclosure.

The Restraints also substantially foreclose the market for all injected prostacyclins. [redacted]. Around 55% of patients on Remodulin receive subcutaneous treatments, and the Restraints prevent Plaintiffs from competing for

those patients. Rao Report at Tab 10. [redacted] As the predicate for his analysis, he relied on a report that was published by the DOJ's Antitrust Division in 2008. That report, however, is "no longer . . . Department of Justice policy." Ex. 911. The DOJ formally withdrew the report in 2009 and announced: "Consumers, businesses, ***courts and antitrust practitioners should not rely on it as Department of Justice antitrust enforcement policy***." *Id*. (emphasis added). [redacted] Gaier 367:19-368:3. [redacted] *Id.* at 383:5-387:15. Dr. Gaier ultimately conceded that outside of what is described in the 2008 report, he had [redacted] *Id*. at 391:17-392:13. His opinions therefore lack rigor and may be ignored.

B. Defendants' Justifications for the Restraints Are Pretextual and Ignore Less Restrictive Alternatives

Defendants have previously argued cartridges would not exist today without UTC's investment in CADD-MS 3 pumps, which it was only willing to make with the Restraints in place. *See* ECF 53-1 at 2. Dr. Gaier also has suggested the Restraints were necessary to obtain UTC's commitment to purchase pumps and

cartridges and therefore they are pro-competitive because they expanded output for pumps and cartridges. These after-the-fact rationalizations are meritless.

There is no evidence that the Restraints were needed to expand the supply of pumps. The truth is the opposite: [redacted]

The same thing can be said for cartridges. There is no evidence that the Restraints were necessary to expand Smiths' capacity to manufacture cartridges or that UTC would not have committed to buy cartridges without the Restraints. Cartridges are manufactured from a resin [redacted] Walker 46:9-47:11; Moomaw 244:5-17. [redacted], Gencheff 123:14-21; Ex. 74 at 844-45; Ex. 75 at 390. In December 2016, however, Smiths found [redacted] Walker 46:14-17; Gencheff

148:24-149:6. [redacted] Ex. 79 at 532; Gencheff 154:16-155:13, 158:2-18. [redacted] Ex. 76 at 549-50; Ex. 205 at 328; Walker 125:1-9, 145:2-18. [redacted]

Any claim that the Restraints were necessary to protect UTC's "investment" from "freeriding" also fails. [redacted] Moreover, a freeriding argument could never justify the Restraints. Federal antitrust laws are primarily concerned with protecting "interbrand" competition (*i.e.*, among ***different brands*** of the same type of product). *Leegin Creative Leather Prods. v. PSKS, Inc.*, 551 U.S. 877, 890-91 (2007). Although courts have recognized limits on "intrabrand" competition (*i.e.*, among distributors of the ***same brand*** of a product) may ***enhance*** interbrand competition between sellers of different competing products, *e.g.*, *Cont'l T.V. Inc. v. GTE Sylvania Inc.*, 433 U.S. 36, 51-52, 54 (1977), the Restraints have the opposite intent and effect. Rather than giving UTC an advantage over other suppliers of the

same brand of product, the Restraints eliminate UTC's competition altogether.[5]

There also is no evidence the Restraints are necessary to preserve access to cartridges for patients on Remodulin. [redacted] Benkowitz 119:8-120:7. [redacted] (especially not now, in 2019).

Finally, even if Defendants' purported justification for the Restraints was valid, there are less restrictive options that Defendants should have adopted to ensure cartridges were available to patients on Remodulin. [redacted]

[5] Dr. Gaier's freeriding opinions also are unreliable. [redacted]

II. Plaintiffs Are Suffering Irreparable Harm

Irreparable harm includes "loss of goodwill, damage to reputation, and loss of business opportunities." *Celsis In Vitro, Inc. v. CellzDirect, Inc.,* 664 F.3d 922, 930 (Fed. Cir. 2012). Absent an injunction, Plaintiffs have and will suffer irreparable harm. Plaintiffs are breaking new ground with the first generic alternative to Remodulin. Plaintiffs committed to specialty pharmacies and patients that they can reliably deliver a therapeutic equivalent to Remodulin, on-time supplies, and the same level of support and resources that patients on Remodulin receive. The Restraints create the perception that Plaintiffs cannot meet those commitments because they cannot supply subcutaneous patients. That perception will inflict irrevocable damage to Plaintiffs' reputation. *See*, *e.g.*, *Byrne v. Calastro*, 205 F. App'x 10, 16 (3d Cir. 2006); *URL Pharma, Inc. v. Reckitt Benckiser Inc.*, 2016 WL 1592695, at *8-11 (E.D. Pa. Apr. 20, 2016) (plaintiffs' loss of the "ability to penetrate the over-the-counter market and establish itself as a legitimate generic provider of a top-selling drug" constituted irreparable harm).

The failure of generic Flolan illustrates how damaging the Restraints will be to Plaintiffs. In 2008, Teva launched the first generic version of Flolan. Ex. 1016 at 6. After launch, Teva encountered manufacturing issues, which led to supply disruptions for the entire market. *Id*. [redacted] 12; Jeffs

163:6-164:7. Teva never recovered from that reputational hit, and generic Flolan never gained traction in the marketplace. It is now considered a [redacted] Ex. 1016 at 6; Ex. 1017 at 12; Jeffs 155:18-21.

It is no coincidence that [redacted] *See*, *e.g.*, Ex. 254 at 120. UTC implemented the Restraints to create the same sort of uncertainty around the supply of generic Remodulin that plagued generic Flolan. As more time passes, uncertainty surrounding Plaintiffs' drug will become permanent. Plaintiffs will not recover from that irreparable harm to their reputation, and it will be difficult, if not impossible, for them to gain and maintain a toehold in the market. That reputational harm cannot be easily quantified or addressed with money damages.

III. The Injunction Will Not Harm Defendants

Defendants will not be unfairly prejudiced by the issuance of an injunction. The injunction would not stop Defendants from selling cartridges or Remodulin. [redacted]

IV. The Public Interest Weighs Heavily in Favor of an Injunction

"[T]he public interest would be particularly disadvantaged by permitting [UTC] to extend its market exclusivity" through unlawful restrictions that frustrate

one of the principal goals of the Hatch-Waxman Act, which is to "encourage generic drug entry into the marketplace." *In re Lipitor Antitrust Litig.*, 868 F.3d 231, 240 (3d Cir. 2017). Eliminating the Restraints would promote competition, and benefit patients, healthcare providers, and payors, by driving down the cost of treatment. Thus, the public interest weighs in favor of an injunction.

V. Defendants' Other Anticipated Arguments Are Meritless

To obtain an expedited hearing, Plaintiffs waived their right to a reply. Plaintiffs therefore address other anticipated arguments from Defendants below.

First, Defendants may argue other pumps are viable alternatives to the CADD-MS 3 for subcutaneous infusions of treprostinil. [redacted]

Second, Defendants may argue Plaintiffs could just design their own pump or modify an existing pump to administer subcutaneous infusions of treprostinil. These contentions have been refuted by Plaintiffs' medical device expert, Dr. John Collins. Dr. Collins will testify that development of a new, suitable alternative to the CADD-MS 3 would require at least [redacted] and cost [redacted] dollars. Collins Decl.

¶¶ 29-35. That is consistent with Plaintiffs' understanding. deGoa Aff. ¶ 20.

Third, Defendants may argue Plaintiffs should have known that they would encounter problems related to cartridges and should have accounted for them prior to launching generic treprostinil.[6] But contrary to what Defendants argued in their motion to dismiss, Smiths did not announce in 2015 that it planned to stop manufacturing cartridges. *See*, *e.g.*, ECF 53-1 at 13. [redacted] Walker 84:13-18. In 2015, Smiths [redacted] Ex. 69 at 924; Walker 81:2-8, 119:1-120:10. The 2015 notice [redacted] Ex. 69. The same notice [redacted] *Id*. [redacted]

Moreover, neither Sandoz nor RareGen had actual notice of the Restraints

[6] Defendants' purported expert [redacted] Plaintiffs will establish, however, that Mr. Talpade is not qualified to offer his opinions. [redacted]

until 2019. A Sandoz employee, Yaping Zhu, had several discussions with Smiths in 2016, and Smiths told her the CADD-MS 3 pump had been discontinued. Ex. 12 at 125. Zhu testified, however, that she never discussed cartridges with Smiths, or restrictions on their use. Zhu 263:22-264:6. There is no evidence to the contrary. Ex. 82; Gencheff 175:16-24; Walker 130:2-9, 131:2-24. RareGen also did not have notice of the Restraints. RareGen is affiliated with two former UTC employees: Roger Jeffs and Scott Moomaw. Both of them left UTC in 2016, before the Restraints were conceived or imposed. Moomaw 20:12-17; Jeffs 7:11-20. They have testified that they had no knowledge of the Restraints before joining RareGen. Jeffs 72:7-73:4, 138:11-16, 278:3-5; Moomaw 151:12-17. [redacted]

There are additional reasons Plaintiffs would not have anticipated the 2019 Restraints. [redacted], in 2017 and 2018, the specialty pharmacies assured Plaintiffs that [redacted]. *See, e.g.*, Ex. 906 (notes from 2017 meeting with Accredo); Ex. 314 (2018 email from Accredo).

Fourth, Defendants may argue that Plaintiffs should have developed their

own cartridges before entering the market. But prior to January 2019, Plaintiffs had no reason to believe that generic treprostinil patients would not be able to access cartridges. Nonetheless, upon learning of the Restraints, RareGen dedicated substantial resources to [redacted] Defendants no doubt would have preferred for Plaintiffs to stay on the sidelines and defer the launch of generic treprostinil until each of those questions is definitively answered. That delay, however, would have exacerbated the harm to patients, and Plaintiffs, caused by the Restraints.

Fifth, Defendants may argue Plaintiffs' consideration of exclusivity arrangements for the RareGen cartridge confirms Defendants' conduct is lawful. But Plaintiffs have not adopted any restrictions on cartridge use. deGoa Aff. ¶ 25. And even if they had, Plaintiffs lack market power. Thus, exclusive contracts for RareGen's own, internally-developed cartridges would not impede competition.

CONCLUSION

For all the reasons stated herein, Plaintiffs respectfully ask the Court to issue a preliminary injunction that prohibits Defendants from enforcing the Restraints.